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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	29

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,815	Applicant(s) NIBBERING ET AL.	
	Examiner Sheridan K Snedden	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-60* is/are pending in the application.

4a) Of the above claim(s) *35-40,44,48,50-54 and 56-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-34,41-43,45-47,49,55 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of invention III, claims 41-43, 45, 47, 49, and 60 is acknowledged. Election was made **with** traverse in Paper No. 28. Upon further consideration, inventions I and III are rejoined. Claims 35-40, 44, 48, 50-54 and 56-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 28-34, 41-43, 45-47, 49, 55 and 60 are under examination.

Information Disclosure Statement

2. Insofar as applicant filed an Information Disclosure Statement on 21 August 2001, te Form PTO-1449 is missing from the application and the references are removed from consideration. These references would be considered upon resubmission of PTO-1449.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-32, 34, 41-43, 45-47, 49, 55 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins of SEQ ID NO: 1-9, does not reasonably provide enablement for all sequences with at least 3 contiguous base pairs derived from ubiquicidine. The specification does not give any guidance as to the structure and functional relationships for the full range existing sequences (i.e., derivatives and variations),

which would maintain antimicrobial activity. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the breadth of the claims,
3. the state of the prior art,
4. the predictability or lack thereof in the art,
5. the amount of direction or guidance present,
6. the presence or absence of working examples,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

2) the breadth of the claims;

In the instant case, the claims recite proteins and protein fragments for use in a method of treating infection. The claims are directed to a fragment derived from SEQ ID NO: 1 of at least 3 continuous amino acids present in SEQ ID NO: 1. The breadth of the claims would include all peptides derived from SEQ ID NO: 1 that would have at least 3 continuous resides of SEQ ID NO: 1.

3) the state of the prior art;

4) the predictability or unpredictability of the art;

The prior art teaches ubiquitin, ubiquitin-like and ribosomal proteins useful in treatment of infection (see for example, US 6319503). Fragments from these peptides are used and employed in treatment protocols, however, the amino acids sequence differ significantly from that of SEQ ID NO: 1. There are no examples of a peptide derived from SEQ ID NO: 1 wherein only 3 continuous residues maintain the requisite biological action.

Given the diversity of the protein sequences that posses similar activity, as seen from the properties of ubiquitin, ubiquitin-like and ribosomal proteins, there is no predictability in what sequence of 3 amino acids would posses the desired function for use in the treatment of infection. A person of skill in the art would have to rely on the teachings of the current invention on how to make and use the claims peptide fragments. However, there is no guidance in the specification or prior art that would lead a person of skill in the art to predictable results in using any 3 continuous residues of SEQ ID NO: 1. The instant specification presents no description of criteria used in selection of tri-peptides nor what the sequence of the derivatives would have been. There is no apparent disclosed selection

criteria which would result in undue experimentation for one of skill in the art to practice the invention.

5) the amount of direction or guidance presented;

6) the presence or absence of working examples;

The specification and claims provide examples of peptide fragments derived from SEQ ID NO: 1 referred to in the claims as SEQ ID NO: 2-5 and 7-9. The size of these fragments range from 6 to 18 amino acids in length. No fragment of 3 amino acids in length is taught.

7) the quantity of experimentation necessary;

The courts have interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). As such, the quality of experimentation necessary to identify and qualify all sequences containing 3 continuous amino acids of SEQ ID NO: 1 is undue.

8) the relative skill of those skilled in the art;

In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a PhD or a person with several years of experience in the art. As the cited art would point to, even with a level of skill in the art that is high, predictability of the results is not invariable.

In consideration of each of factors 1 – 8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28-34, 41-43, 45-47, 49, 55 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 and dependent claims thereto are indefinite as the phrase "exception of the peptides" makes it unclear as to if the peptides are excluded or included. Applicant may consider the phrase "does not include."

Claim 30 is indefinite because it is unclear as to whether or not the claim is directed to a peptide consisting of the recited fragments or merely comprises the recited fragments.

Claim 34 is indefinite as the meaning of "-" and "--" is unclear.

Claims 41 is indefinite as the method appears to be incomplete. There is no endpoint for the process and it is unclear what the treatment is suppose to accomplish. Note that simply administering, as is claimed, does not per se nor necessarily result in positive treatment results, thus the claim would appear to be incomplete. Claims 41-43, 45, 47, and 55 are indefinite as they depend from claim 41 and do not clarify the ambiguity. See also same issue in claims 49 and 60.

The phrase "caused by a cause" in claim 45 renders the claims indefinite.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "parasite" in claim 45 is used by the claim to mean "microbial", while the accepted meaning

includes various organisms that are not microbial, *e.g.* tapeworms. The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-33, 46 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikoshiba (JP 08176193 A). Mikoshiba teach a peptide identical to SEQ ID NO: 1 for a continuous series of 41 amino acids (regarding claims 28-33). Claim 46 of the instant application recites an inherent property of the peptide taught by Mikoshiba, which is also administered with an excipient (regarding claim 55). Thus, the reference anticipates the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
September 22, 2003

SKS

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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